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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,669	12/12/2005	Kexin Xu	7605 P 002	4371

7590 09/14/2009

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EXAMINER	
WINAKUR, ERIC FRANK	
ART UNIT	**PAPER NUMBER**
3768	

MAIL DATE	DELIVERY MODE
09/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/532,669	XU ET AL.
	Examiner	**Art Unit**
	AHMED ELHASSAN	4138

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final. .

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-15 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 4/26/05 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5/27/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: on page 11, line 25 gating baffle "7 "is mistyped as "1", also spatial chopper "7a" is mistyped as "1a". The same mistyping is on lines 1 and 2 of page 12. On line 18, of page 4, "receiving unit" should be "incident unit" instead. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 2, 3, 4, 5, 6, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keller (US 2006/018040) in view of Lorenz (US 7,317, 938).

Regarding claim 1, Keller discloses a composite spectral measurement ([0012], lines 5-7) method ([0002], line 2) comprising an incident unit (ensemble 102 & 103, FIG. 1) a probe ([0196], line 7) a receiving unit (inherent in the spectral calculation methods, "spectral signature", [0187], line 1) and a data processing unit (FIG. 1, No. 700), wherein an incident light source in said incident unit is a composite light source, which is comprised of a continuous light source and a discrete light source; that is, the

continuous light source includes at least one single wavelength light source ([0013], lines 6 & 12-13) , or is composed of a continuous light source and continuous light sources with different characteristics;

said probe may make the continuous light source and the discrete light source to conduct light incidence and receipt at one and the same position and decide a layout of optical lengths according to light intensities of respective light sources (inherent in spectral measurement applying scatter-compensated Beers law expression to account for the longer path length) , or may make the continuous light source and the discrete light source to conduct light incidence and receipt at different positions, and decide a layout of optical lengths according to light intensities of respective light sources.

the composite spectral method is implemented in said receiving unit, which includes adding the continuous and discrete spectra overlapped and adding the continuous and discrete spectra non-overlapped (inherent in "comparing various spectral parameters across a spectral range", [0158], lines 2-3); in said data processing unit, the composite spectra received by the receiving unit are analyzed ([0191], line 1) and calculated by using a mathematical model ([0293], "calibrated", line 2).

Keller lacks using the mathematical model for deriving the concentration of a certain component of interest such as blood glucose

Lorenz teaches using a mathematical model (("calibration", col. 9, line 39) for deriving the concentration of a certain component of interest such as blood glucose (col. 9, lines 39-40).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Keller with using the mathematical model for deriving the concentration of a certain component of interest such as blood glucose, in view of Lorenz with the motivation to non-invasively monitor glucose levels of diabetes patients.

Regarding claim 2, Keller-Lorenz as applied to claim 1, includes that the discrete light source is a light- emitting diode LED (Keller; [0090], line 3) , the wavelength range of said continuous light source can be any wavelength band within 0.8-2.5μm (Keller; "950 nm", [0218], line 7), while for that of said discrete light source, several wavelengths within or beyond the wavelength range (Keller; "950 nm", [0218], line 7) of said continuous light source, that the discrete light source and continuous light source ([0015]), are split using an AOTF ([0145], lines 10-11).

Regarding claim 3, Keller-Lorenz as applied to claim 1, includes a composite spectral measurement method wherein switching of composite light source is achieved by circuit switching controlled by AOTF ([0145], lines 10-11) and a computer (FIG. 1, No. 700).

Regarding claim 4, Keller-Lorenz as applied to claim 1 includes that the sequential control can be achieved in two ways: one is to separately measure the continuous spectra and discrete spectra, that is, first measure the continuous spectra, then the discrete spectra, or the discrete spectra first while the continuous spectra later; the other one is cross measurement, that is, the continuous spectra and discrete spectra are alternately measured in the order of wavelengths (inherent in subsystem No 500, FIG 1, to filter pre-selected ,[0015], lines 7-9, combinations of discrete and/or

continuous wavelengths or wavelength bands , before passing data to computer No. 700, FIG 5, for spectral analysis , [0024], lines 13-14).

Regarding claims 5, 6, 7, and 8 Keller-Lorenz as applied to claim 1, includes filtering pre-selected combinations, ("pre-selected", [0015], line 8 & "combinations", [0144] , line 10), of continuous and discrete wavelengths, ([0015]), using AOTF, ([0145], lines 10-11), and converting the light signal to an electric signal (inherent in spectral data processing in computer) via processing circuits with different gains (inherent in signal amplification within computer, No. 700, FIG. 1) to generate spectra according to the combinations of filtered wavelengths (subsystem No. 500, FIG. 1, houses filters and feeds output to computer No. 700, FIG. 1, where spectra are generated and analyzed, [0158], lines 1-3).

3. Claims 9, 10, 11, 12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keller in view of Lorenz, further in view of Hannigan (US 5,999,081).

Regarding claim 9, Keller discloses a spectral detection instrument (FIG. 1) using the composite spectral measurement method ([0002], line 2), comprising three modules, an incident unit (Ia), (ensemble 102 & 103, FIG. 1)
a probe ([0196], line 7) and a receiving unit (Ib) (inherent in the spectral calculation methods, "spectral signature", [0187], line 1), wherein an incident light path of said probe (1) is composed of an incident fiber ([0027, line 2) of said continuous light source and an incident fiber ((same fiber; [0027, line 2)) of said discrete light source ; an AOTF crystal (crystal is inherent in AOTF; [0145], lines 10-11) is used for light-splitting ([0145], lines 10-11); said discrete light source can be one (Keller; [0090], line 3) or several LD's

of different wavelengths, a set of focusing lens (No. 103, FIG. 1) is used for LD with said transmission fiber of said discrete light source, an LD gating baffle (Anthony; between slits No. 202a FIG. 7, on rotating disk No. 200, FIG. 6) controlled by a spatial chopper (Anthony; ensemble No. 200, 300 & 600 FIG. 7) is chosen as a gating switch; a receiving light path of the probe is configured through a connection between a receiving fiber and photoelectric conversion and processing circuits (FIG. 1, No. 500, since it coverts inputted light signal from No. 105 into outputted electric signal fed by cable to computer No. 700) with different gains (inherent in photoelectric conversion and signal amplification by No. 500, FIG. 1); after that, a control function of a controller is achieved by choosing, by a computer (No. 700, FIG. 1), output signals in corresponding channels of the photoelectric conversion and processing circuits ; and a fine tuning alignment device (inherent to controlling filters with No. 500, FIG. 1), the output signal is transferred to an NI terminal board or a shielded joint (inherent in connector where cable from FIG. 1, No. 500 interfaces computer No. 700, since a computer casing is grounded), and finally a relevant data processing is performed by a computer (, No. 700, FIG. 1).

Keller-Lorenz, as applied to claim 9, lacks that unit NO. 500, FIG. 1 where photoelectric converted signals are processed, before outputting to shielded joint at computer 700/cable interface , has circuits with a shielded thermal equilibrium cover.

Hannigan teaches a thermal equilibrium shielding (col. 2, lines 33-34).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Keller-Lorenz, with a shielded thermal equilibrium cover for processing circuits

in unit No. 500, FIG. 1, in view of Hannigan, with the motivation to improve measurement by blocking radio frequency interference, RFI and electromagnetic interference, EMI.

Regarding claim 10, Keller-Lorenz-Hannigan as applied to claim 9 includes that incident light path of said discrete light source of said incident unit is light-split by the AOTF (Keller; anyone of the filters of MWIOS NO. 500, FIG.1, can be an AOTF crystal , [0145], lines 10-11) selectively similarly to said continuous light source (Keller; MWIOS No. 500, FIG. 1 includes a number of filters , [0015], line 7, which filter continuous or discrete wavelengths, [0015], line 9).

Regarding claim 11, Keller-Lorenz-Hannigan as applied to claim 9, includes that the spectral detection instrument using the composite spectral measurement method wherein receiving light path of said probe is configured through a direct connection (Keller; "flexible endoscope along with integrated fiber optic illumination with MWIOS No. 500", [0246], lines 4-5 & FIG. 1) of said receiving fiber with said gain-tunable photoelectric conversion and processing circuit ; after being processed by said shielded thermal equilibrium cover and said fine tuning device , the output signal is transferred to said NI terminal board or said shielded joint, and finally said relevant data processing is performed by said computer .

Regarding claim 12, Keller-Lorenz-Hannigan as applied to claim 9, includes that the spectral detection instrument using the composite spectral measurement method wherein said probe, said continuous light source and said discrete light source are placed at one and the same position (Keller, FIG. 1, 102) ; in the central position

(inherent in maximizing light intensity & minimizing attenuation in fiber optic, [0027], line 2]) of said probe, said discrete light source transmission fiber and said continuous light source transmission fiber (inherent in having a continuous & a discrete simultaneously-operable , [0016] & [0017], light sources and a fiber optic cable for remote examination [0112], line 1) are placed; said receiving fiber (Keller; "optical fiber for transmitting reflected light", [0027, lines 2-4) is provided in an external ring (Keller; a circular partition, around a fiber optics terminal, for preventing incident light from directly interfering with tissue-reflected light, is inherent to "associated optics for transmitting light reflected from substrate", [0027], lines 2-4) of said probe; such a layout effectively concentrates incident light intensity, and simultaneously prevents a majority of stray light that hasn't been scattered by deep tissue but only reflected by surface from being received.

Regarding claim 14 Keller-Lorenz-Hannigan as applied to claim 9 includes the spectral detection instrument using the composite spectral measurement method wherein said discrete light source LD in the incident unit of said non-invasive detection instrument is coupled with an optical fiber (" light emitted from fiber optic cable", [0113], line 6), wherein said discrete light source LD is coupled with said discrete light source incident fiber through said focusing lens ([0113], line 5 & FIG. 1, No. 103).

4. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keller in view of Lorenz, and Hannigan, further in view of Durkin (US 6678541), further in view of Acosta (US 7133710).

Regarding claim 13 Keller-Lorenz-Hannigan as applied to claim 9 includes the spectral detection instrument using the composite spectral measurement method according wherein said continuous light source and discrete light source are place at different positions (Keller; "continuous or point light sources in a pattern", [0087], lines 11-12).

Keller lacks that discrete light source transmission fiber is placed in the centre of said probe, and said inner receiving fiber (19) is placed in its internal ring, while said outer receiving fiber (20) is placed in its external ring, and said continuous light source transmission fiber (2) is placed in it middle ring.

Durkin teaches that an illuminating fiber is placed in the center of a probe (No. 802, FIG. 8) while detection fibers (No. 806, FIG. 8) are radially arranged, with spacers (No. 804, FIG. 8) arranged as radial separation rings (FIG. 8).

Acosta teaches a probe with different fiber-optic guided (col. 11, line 59) light sources radially arranged (FIG. 8).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Keller-Lorenz-Hannigan with a centrally illuminated light source in view of Durkin, while placing other light sources radially with spacers delineating rings in view of Acosta, with the motivation to improve spectroscopy measurement by having narrowest bandwidth wavelengths (i.e discrete) with highest absorption at location where intensity is highest (i.e center).

5. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keller in view of Lorenz and Hannigan, and further in view of Rutchti et al (US 6,990,364)

Regarding claim 15 Keller-Lorenz-Hannigan as applied to claim 9 lacks that the spectral detection instrument using the composite spectral measurement method wherein blood glucose measuring, optional wavelengths of said discrete light source are 980nm, 1310nm, 1550nm, 1610nm and 1650nm.

Ruchti teaches a spectral glucose measurement device with a range of 700-2500 nm (col. 11, line 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Keller-Lorenz-Hannigan with selecting wavelengths within Rutchti's range for the discrete light sources, with the motivation to improve measurement by increasing light intensity at wavelengths where glucose absorption is highest.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AHMED ELHASSAN whose telephone number is (571)270-7390. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Melba Bumgarner can be reached on 571-272-4709. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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